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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,521	07/20/2001	Jack V. Smith		2103

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05/05/2004

JACK V. SMITH
P.O. BOX 156
Arden, NC 28704

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/910,521		SMITH, JACK V.	
	Examiner		Art Unit	
	Arlen Soderquist		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003 (copy faxed on 2-17-04).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Appendixes A & B</u> |

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1. From the response filed December 31, 2003 (copy faxed on February 17, 2004), it appears that there are some differences between the claims on file at the US Patent & Trademark Office and those that applicant believes are on file in this application, Serial Number 09/910,521. This application was filed July 20, 2001. There were five claims (see Appendix A) filed with this application and the Office has no record of any changes being made to these claims. On page 2 of the response, applicant makes reference to this divisional application being filed with 2 claims on March 21, 2003. The office does not have any record of either a new application with applicant as the inventor or an amendment in this application being filed on that date. If applicant is able to clear up this discrepancy, he is invited to call the examiner at the number listed at the end of this application. Since the examiner cannot examine claims that are not in the application, the claims of Appendix A will again be examined in this office action. Applicant's response will be considered by the examiner relative to the claims of record in this application.

Since these are the claims of record and applicant has received an action on the merits, claims directed to an invention that is independent or distinct from the invention originally claimed will not be examined in this application. See 37 CFR 1.142(b) and MPEP § 821.03. Should applicant wish to submit claims directed to an invention that is independent or distinct from the instantly claimed invention, the proper way to do this is to file a continuing application. Because of applicant's *pro se* status, the following is a guide to the format to be used in referring to the prior applications in the new application.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications. An example of a proper benefit claim is "this application is a continuation of prior Application No. ---, filed ---." When applicant desires the benefit of more than one application, a reference to each prior application must be present. Also, the current status of all nonprovisional parent applications referenced should be included. An example of how this benefit claim would look for a continuation of the instant application is "this application is a continuation of prior Application No. 09/910,521, filed July 20, 2001, now abandoned, which is a divisional of prior Application No. 09/556,395, filed April 24, 2000, now

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US Patent 6,537,823.”

Additionally the format for making amendments in an application has changed as of July 30, 2003. Examiner has included an explanation of the format so that future responses will not be returned because applicant has failed to use the required amendment format. This explanation of the required amendment format is found in Appendix B.

2. In the claims examiner is treating the term bromine as it is defined page 6, lines 14-27 of the instant specification to include bromine, bromates, analogs of these compounds and other compounds containing bromine capable of producing an oxidative reaction in an aqueous solution.

3. This application discloses and claims only subject matter disclosed in prior Application No. 09/556,395, filed April 24, 2000, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

4. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 attempts to broaden the coverage of claim 1 by increasing the types of samples used while claim 1 is limited to urine. For examination purposes claim 1 will be treated to cover all of the samples outlined in claim 3.

5. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 5 contain a Markush group which should have all of the elements therein listed using “and” instead of “or” as the final linker. For example, in claim 4, the proper form of the last two compounds in the first group is “aminobenzoic acid and 4-aminoantipyrine”.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldan in view of Douglas and Dunn. In the abstract Eldan teaches biological monitoring of workers' exposure to bromine. The use of serum bromine (referring to any form of Br) concentration (SeBr) as a measure of exposure was examined in an occupational cohort. Associations with work site, department type, chemical handling, and occupation, as proxy measures of exposure, were studied. SeBr was associated with all of these measures. SeBr was also associated with various demographic characteristics (age, country of origin, and education) in men. In women, there was no association between SeBr and age, country of origin, or education. The use of SeBr as a measure of exposure is discussed. The conclusion is that exposure to bromine can be assessed by regular monitoring of SeBr. Eldan does not teach measuring bromine with a test strip or dipstick type of device and does not teach other types of biological fluids for measuring of bromine.

In the published application Douglas teaches a direct reading chemical test strip for aqueous solutions. A chemical test strip is described that is comprised of a support layer, a first assay area, a second assay area, and a hydrophobic zone positioned between the first assay area and the second assay area. The first and second assay areas are attached to the support layer and comprise an absorbent matrix. The first assay area includes a first test reagent absorbed in its matrix that changes color in response to a first concentration of an analyte such as free available chlorine (Cl). The second assay area includes a second test reagent absorbed in its matrix that changes color in response to a second concentration of the analyte. Interpretation of the test strip can be facilitated by printing information on the assay areas, which is more visible after the color change than before the color change. An example (example 1) describes a test strip for the

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detection of Cl in an aqueous sample such as pool or hot tub water by using 3,5,3',5'-tetramethylbenzidine and syringaldazine in the presence of buffers as color reagents that can detect different concentrations of Cl on the same strip. Page 4 lines 12-22 discuss the device shown in figure 1 and include that any type of chemical system capable of detecting aqueous analytes can be used including those for chlorine and bromine. Example 2 is directed toward bromine determinations. In the background section Douglas discusses problems with using photometric instruments (cost, calibration and maintenance) and with prior dipstick type measuring devices (color matching errors) overcome with the disclosed devices.

In the abstract Dunn discusses detection of bromate in blood and urine. To 2 ml. of plasma or urine, add 1 ml. of 4 N HCl. Centrifuge. Add 0.1 ml. of 0.01% aqueous solution of Evans blue. Immediate fading of the blue color indicates the presence of bromate at a level of 1 mg. % or more. Nitrite interferes but may be removed by the addition of 0.25 g. of urea.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the test strip of Douglas in the method of Eldan because of the ability to measure bromine in aqueous samples and the advantages of the detection as taught by Douglas. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the measurements on other biological fluids such as urine because as shown by Dunn there would be an expectation of the presence of bromine compounds in urine and the ability to make a colorimetric measurement of the level of bromine compounds present.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,537,823. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are of a scope that completely encompasses the patented claims.

10. Applicant's arguments filed December 31, 2003 (copy faxed on February 17, 2004) have been fully considered but they are not persuasive. First, as noted above, examiner cannot search or examine claims that are not of record in the application. This also is relevant to giving constructive assistance to applicant, since examiner does not know what other inventions applicant considers to be in this application or would like to claim based on the disclosure of this application. As a result examiner has not searched or examined any other invention that might be found in the disclosure of this application to the extent that a determination can be made on its patentability.

Relative to the obviousness-type patenting rejection, the claims would need to either be amended to the point that obviousness-type double patenting is no longer an issue or applicant can submit a terminal disclaimer as explained above.

Relative to the art rejection, examiner points out that applicant used open language in drafting the claims. This does not limit the claims beyond the elements required in the language of the claims. In this respect the claims do not limit or define the source of the bromine in the urine. As a result the claims have been treated as the bromine can come from any source such as exposure to bromine in the workplace. The claims are also not limited to the method being conducted in conjunction with a test for drugs-of abuse. In other words, the claimed method is a method for measuring bromine in urine irrespective of any other test or analysis that may be performed on the urine sample. Additionally the claims use the term bromine but applicant has broadly defined the term bromine in the specification to include bromine, bromates, analogs of these compounds and other compounds containing bromine capable of producing an oxidative reaction in an aqueous solution. Thus the term bromine can include other forms of bromine that would naturally be found in urine. These distinctions between the scope of the claims and the scope of the arguments of applicant form one reason that the arguments are not persuasive.

Relative to the components of the Douglas and Dunn references, claim 4 was not rejected in the art rejection including these references. That claim is the only claim that defines/limits the

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indicators used. All other claims do not limit the indicator used and as such are within the claim scope.

Unexpected results require that a comparison be made to show that the results differ from that which would be expected. Applicant has not provided this comparison, so there is not a showing of unexpected results as argued. In response to applicant's argument that invention solves a different problem, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$165.00.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection

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unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to reagents for detection of oxidative compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



May 4, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER